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PHARMACEUTICALS, INC., MERCK & CO., INC.

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN FRANCISCO DIVISION

SHERRI KELLERMAN,  
  
Plaintiff,  
  
v.

BAYER HEALTHCARE PHARMACEUTICALS,  
INC.; MERCK & CO., INC.; SCHERING  
CORPORATION; and MCKESSON  
CORPORATION,  
  
Defendants.

Case No.: 3:14-cv-3680 WHA

**ANSWER AND DEFENSES OF  
BAYER HEALTHCARE  
PHARMACEUTICALS, INC.**

**DEMAND FOR JURY TRIAL**

Defendant Bayer HealthCare Pharmaceuticals, Inc. (“Bayer”), for themselves and no other defendants, hereby submits this Answer to Plaintiff Sherri Kellerman’s (“Plaintiff”) Complaint (the “Complaint”).

**FIRST RESPONSE TO “INTRODUCTION”**

1  
2           1.       Paragraph 1 of the Complaint states legal conclusions to which no answer is required.  
3 To the extent a response may be required, Bayer admits that Avelox® is a fluoroquinolone  
4 antibacterial indicated for treating certain bacterial infections in adults ≥ 18 years of age caused by  
5 designated, susceptible bacteria. Except as so stated, Bayer denies the allegations in Paragraph 1 of  
6 the Complaint. Bayer further states that, to the extent the Complaint contains allegations referring to  
7 entities other than Bayer HealthCare Pharmaceuticals, Inc. (individually or collectively) as  
8 “Defendant” and/or “Defendants,” Bayer is not answering the Complaint on behalf of any entities  
9 other than Bayer HealthCare Pharmaceuticals, Inc. and is not answering allegations that are directed  
10 to any entities other than Bayer HealthCare Pharmaceuticals, Inc.

**FIRST RESPONSE TO “PARTIES”**

11  
12           2.       Bayer is without knowledge or information sufficient to form a belief as to the truth  
13 of the allegations in Paragraph 2 of the Complaint concerning Plaintiff’s residence and citizenship  
14 and therefore deny them. The remaining allegations in Paragraph 2 of the Complaint state legal  
15 conclusions to which no answer is required. To the extent that a response is required to the  
16 remaining allegations in Paragraph 2 of the Complaint, Bayer denies the allegations and denies that  
17 Bayer is liable for any damages and that any relief as requested in the Complaint should be granted  
18 against Bayer.

19           3.       Bayer admits that it is a Delaware corporation and states that its principal place of  
20 business is in Whippany, New Jersey.

21           4.       Bayer admits that Bayer Pharmaceuticals Corporation was merged into Bayer  
22 HealthCare Pharmaceuticals, Inc. in January 2008.

23           5.       Paragraph 5 of the Complaint states legal conclusions to which no answer is required.  
24 To the extent a response is required, Bayer admits that it has done business in California. Except as  
25 so stated, Bayer denies the allegations in Paragraph 5 of the Complaint.

26           6.       The allegations in Paragraph 6 of the Complaint are so vague and overbroad that they  
27 cannot be answered with specificity. To the extent the allegations relate to Avelox®, Bayer admits  
28 that it earns revenue from the sales of Avelox® in California. Except as so stated, Bayer deny the

1 allegations in Paragraph 6 of the Complaint.

2 7. The allegations in Paragraph 7 of the Complaint are so vague and overbroad that they  
3 cannot be answered with specificity. The Complaint does not define “acts” or “consequences.” As  
4 such, no response is required. To the extent a response is required, Bayer incorporates its answer to  
5 Paragraph 6 of the Complaint. Except as so stated, Bayer denies the allegations in Paragraph 7 of  
6 the Complaint.

7 8. Bayer admits that it manufactures, labels, supplies, sells, and distributes Avelox® in  
8 the United States. Bayer also admits that it earns revenue from the sales of Avelox®. Except as so  
9 stated, Bayer denies the allegations in Paragraph 8 of the Complaint.

10 9. Paragraph 9 of the Complaint makes allegations against defendants other than Bayer,  
11 so no response from Bayer is required. To the extent that the allegations in Paragraph 9 are directed  
12 at Bayer, they are denied.

13 10. Paragraph 10 of the Complaint makes allegations against defendants other than  
14 Bayer, so no response from Bayer is required. To the extent that the allegations in Paragraph 10 are  
15 directed at Bayer, they are denied.

16 11. Paragraph 11 of the Complaint makes allegations against defendants other than  
17 Bayer, so no response from Bayer is required. To the extent that the allegations in Paragraph 11 are  
18 directed at Bayer, they are denied.

19 12. Paragraph 12 of the Complaint makes allegations against defendants other than  
20 Bayer, so no response from Bayer is required. To the extent that the allegations in Paragraph 12 are  
21 directed at Bayer, they are denied.

22 13. Paragraph 13 of the Complaint makes allegations against defendants other than  
23 Bayer, so no response from Bayer is required. To the extent that the allegations in Paragraph 13 are  
24 directed at Bayer, they are denied.

25 14. Paragraph 14 of the Complaint makes allegations against defendants other than  
26 Bayer, so no response from Bayer is required. To the extent that the allegations in Paragraph 14 are  
27 directed at Bayer, they are denied.

28 15. Paragraph 15 of the Complaint makes allegations against defendants other than

1 Bayer, so no response from Bayer is required. To the extent that the allegations in Paragraph 15 are  
2 directed at Bayer, they are denied.

3 16. Paragraph 16 of the Complaint makes allegations against defendants other than  
4 Bayer, so no response from Bayer is required. To the extent that the allegations in Paragraph 16 are  
5 directed at Bayer, they are denied.

6 17. Paragraph 17 of the Complaint makes allegations against defendants other than  
7 Bayer, so no response from Bayer is required. To the extent that the allegations in Paragraph 17 are  
8 directed at Bayer, they are denied.

9 18. Paragraph 18 of the Complaint makes allegations against defendants other than  
10 Bayer, so no response from Bayer is required. To the extent that the allegations in Paragraph 18 are  
11 directed at Bayer, they are denied.

12 19. Paragraph 19 of the Complaint makes allegations against defendants other than  
13 Bayer, so no response from Bayer is required. To the extent that the allegations in Paragraph 19 are  
14 directed at Bayer, they are denied.

15 20. Bayer admits that Schering Corporation promoted Avelox® in the United States prior  
16 to its acquisition by Merck & Co., Inc. on November 4, 2009. Except as so stated, Bayer denies the  
17 allegations in Paragraph 20 of the Complaint.

18 21. Paragraph 21 of the Complaint makes allegations against defendants other than  
19 Bayer, so no response from Bayer is required. To the extent that the allegations in Paragraph 21 are  
20 directed at Bayer, they are denied.

21 22. Paragraph 22 of the Complaint makes allegations against defendants other than  
22 Bayer, so no response from Bayer is required. To the extent that the allegations in Paragraph 22 are  
23 directed at Bayer, they are denied.

24 23. Paragraph 23 of the Complaint makes allegations against defendants other than  
25 Bayer, so no response from Bayer is required. To the extent that the allegations in Paragraph 23 are  
26 directed at Bayer, they are denied.

27 24. Bayer admits that McKesson Corporation is a distributor of Avelox®. Except as so  
28 stated, Bayer denies the allegations in Paragraph 24 of the Complaint.

1           25.     The allegations in Paragraph 25 of the Complaint are so vague and overbroad that  
2 they cannot be answered with specificity. The Complaint does not define “research services” and  
3 does not specify what, if any, services McKesson Corporation allegedly provided to Bayer. As such,  
4 no response is required. To the extent a response is required, Bayer incorporates its answer to  
5 Paragraph 24 of the Complaint. Except as so stated, Bayer denies the allegations in Paragraph 25 of  
6 the Complaint.

7           26.     Paragraph 26 of the Complaint makes allegations against defendants other than  
8 Bayer, so no response from Bayer is required. To the extent that the allegations in Paragraph 26 are  
9 directed at Bayer, they are denied.

10          27.     Paragraph 27 of the Complaint contains a statement that does not require an  
11 admission or denial, as no allegations are stated.

12          28.     Paragraph 28 of the Complaint states legal conclusions to which no answer is  
13 required. To the extent a response is required, Bayer incorporate its answers to Paragraphs 5 and 6  
14 of the Complaint. Except as so stated, Bayer denies the allegations in Paragraph 28 of the  
15 Complaint.

16          29.     Paragraph 29 of the Complaint states legal conclusions to which no answer is  
17 required. To the extent a response is required, Bayer incorporates its answers to Paragraphs 5 and 6  
18 of the Complaint. Except as so stated, Bayer denies the allegations in Paragraph 29 of the  
19 Complaint.

20          30.     In response to the allegations in Paragraph 30 of the Complaint, Bayer incorporates  
21 its answer to Paragraph 8 of the Complaint. Except as so stated, Bayer denies the allegations in  
22 Paragraph 30 of the Complaint.

23                   **FIRST RESPONSE TO “JURISDICTION AND VENUE”**

24          31.     Paragraph 31 of the Complaint states legal conclusions to which no response is  
25 required. To the extent a response is required, Bayer incorporates its answer to Paragraph 3 of the  
26 Complaint. Bayer further states that the cited statutory provision is in writing, speaks for itself, and  
27 is the best evidence of its terms, and denies any allegations inconsistent therewith. Except as so  
28 stated, Bayer denies the allegations in Paragraph 31 of the Complaint.

1           32. Paragraph 32 of the Complaint states legal conclusions to which no response is  
2 required. Bayer further states that the cited statutory provision is in writing, speaks for itself, and is  
3 the best evidence of its terms, and deny any allegations inconsistent therewith. Except as so stated,  
4 Bayer denies the allegations in Paragraph 32 of the Complaint.

5           33. Paragraph 33 of the Complaint states legal conclusions to which no response is  
6 required. To the extent a response is required, Bayer incorporates its answer to Paragraph 8 of the  
7 Complaint. Bayer further states that the cited statutory provision is in writing, speaks for itself, and  
8 is the best evidence of its terms, and deny any allegations inconsistent therewith. Except as so  
9 stated, Bayer denies the allegations in Paragraph 33 of the Complaint.

10                           **FIRST RESPONSE TO “FACTUAL ALLEGATIONS”**

11           34. In response to the allegations in Paragraph 34 of the Complaint, Bayer incorporates  
12 its answer to Paragraph 8 of the Complaint. Except as so stated, Bayer denies the allegations in  
13 Paragraph 34 of the Complaint.

14           35. Bayer is without knowledge or information sufficient to form a belief as to the truth  
15 of the allegations in Paragraph 35 of the Complaint and therefore denies them.

16           36. Paragraph 36 of the Complaint makes allegations against defendants other than  
17 Bayer, so no response from Bayer is required. To the extent that the allegations in Paragraph 36 are  
18 directed at Bayer, they are denied.

19           37. Bayer admits that the United States Food and Drug Administration (“FDA”)  
20 approved Avelox® for use in the United States on December 10, 1999. Bayer further admits that  
21 Avelox® is the brand name for the antibiotic moxifloxacin.

22           38. Bayer admits that Avelox® is a fluoroquinolone antibacterial indicated for treating  
23 certain bacterial infections in adults  $\geq 18$  years of age caused by designated, susceptible bacteria.  
24 Bayer further admits that Avelox® is administered by oral tablet and IV solution. In response to the  
25 remaining allegations in Paragraph 38 of the Complaint, Bayer incorporates its answer to Paragraph  
26 8 of the Complaint. Except as so stated, Bayer denies the allegations in Paragraph 38 of the  
27 Complaint.

28           39. In response to the allegations in Paragraph 39 of the Complaint, Bayer incorporates

1 its answer to Paragraph 38 of the Complaint. Bayer further admits that the bactericidal action of  
2 moxifloxacin results from inhibition of the topoisomerase II (DNA gyrase) and topoisomerase IV  
3 required for bacterial DNA replication, transcription, repair, and recombination. Except as so stated,  
4 Bayer denies the allegations in Paragraph 39 of the Complaint.

5 40. The allegations in Paragraph 40 of the Complaint are not directed towards Bayer, so  
6 no response from Bayer is required. To the extent a response is required, Bayer is without  
7 knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 40  
8 of the Complaint and therefore denies them.

9 41. The allegations in Paragraph 41 of the Complaint are not directed towards Bayer, so  
10 no response from Bayer is required. To the extent a response is required, Bayer is without  
11 knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 41  
12 of the Complaint and therefore denies them.

13 42. The allegations in Paragraph 42 of the Complaint are not directed towards Bayer, so  
14 no response from Bayer is required. To the extent a response is required, Bayer is without  
15 knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 42  
16 of the Complaint and therefore denies them.

17 43. Bayer admits that it submitted a New Drug Application for Avelox® on December 9,  
18 1998. Except as so stated, Bayer denies the allegations in Paragraph 43 of the Complaint.

19 44. Bayer admits that the patent for Cipro® expired in 2003. Except as so stated, Bayer  
20 denies the allegations in Paragraph 44 of the Complaint.

21 45. Bayer denies the allegations in Paragraph 45 of the Complaint.

22 46. Bayer admits that it maintains a website for Avelox®, the content of which speaks for  
23 itself. Except as so stated, Bayer denies the allegations in Paragraph 46 of the Complaint.

24 47. Bayer denies the allegations in Paragraph 47 of the Complaint.

25 48. Bayer denies the allegations in Paragraph 48 of the Complaint.

26 49. Bayer denies the allegations in Paragraph 49 of the Complaint.

27 50. Bayer admits that Avelox® has product labeling, the content of which speaks for  
28 itself. Bayer denies that the warnings for Avelox® were inadequate and denies the remaining

1 allegations in Paragraph 50 of the Complaint.

2 51. In response to the allegations in Paragraph 51 of the Complaint, Bayer incorporates  
3 its answer to Paragraph 50 of the Complaint.

4 52. Bayer states that in 1999, Avelox® was approved by the FDA as safe and effective  
5 for the uses and indications set forth in the label and package insert and that, subsequently, any  
6 labeling changes or additions were made per FDA approval. Bayer further states that no “Dear  
7 Doctor” letters have been issued in the United States that are specific to Avelox and peripheral  
8 neuropathy. Moreover, the FDA has not requested that such a letter be disseminated. Bayer denies  
9 the remaining allegations in Paragraph 52 of the Complaint.

10 53. Bayer denies the allegations in Paragraph 53 of the Complaint.

11 54. Bayer states that the literature referenced in Paragraph 54 of the Complaint speaks for  
12 itself, and denies the allegations in Paragraph 54 to the extent they are inconsistent with the contents  
13 of the literature. Except as so stated, Bayer denies the allegations in Paragraph 54 of the Complaint.

14 55. Bayer states that the literature referenced in Paragraph 55 of the Complaint speaks for  
15 itself, and denies the allegations in Paragraph 55 to the extent they are inconsistent with the contents  
16 of the literature. Except as so stated, Bayer denies the allegations in Paragraph 55 of the Complaint.

17 56. Bayer states that the literature referenced in Paragraph 56 of the Complaint speaks for  
18 itself, and denies the allegations in Paragraph 56 to the extent they are inconsistent with the contents  
19 of the literature. Except as so stated, Bayer denies the allegations in Paragraph 56 of the Complaint.

20 57. Bayer states that the literature referenced in Paragraph 57 of the Complaint speaks for  
21 itself, and denies the allegations in Paragraph 57 to the extent they are inconsistent with the contents  
22 of the literature. Except as so stated, Bayer denies the allegations in Paragraph 57 of the Complaint.

23 58. Bayer states that adverse event reports speak for themselves, and denies the  
24 allegations in Paragraph 58 of the Complaint to the extent they are inconsistent with the adverse  
25 event reports. Bayer admits that it complied with all FDA requirements and regulations regarding  
26 the warnings contained in Avelox®’s label. Except as so stated, Bayer denies the allegations in  
27 Paragraph 58 of the Complaint.

28 59. Bayer states that adverse event reports speak for themselves, and denies the



1 allegations in Paragraph 59 of the Complaint to the extent they are inconsistent with the adverse  
2 event reports. Bayer admits that it complied with all FDA requirements and regulations regarding  
3 the warnings contained in Avelox®'s label. Except as so stated, Bayer denies the allegations in  
4 Paragraph 59 of the Complaint.

5 60. Bayer admits that the product labeling for Avelox® was amended in September 2004.  
6 Bayer further states that the content of the product labeling for Avelox® speaks for itself. Bayer  
7 denies that the warnings for Avelox® were inadequate and denies the remaining allegations in  
8 Paragraph 60 of the Complaint.

9 61. Bayer denies the allegations in Paragraph 61 of the Complaint.

10 62. Bayer denies the allegations in Paragraph 62 of the Complaint.

11 63. Bayer denies the allegations in Paragraph 63 of the Complaint.

12 64. Bayer admits that Avelox® has been approved by the FDA as safe and effective for  
13 the uses and indications set forth in the label and package insert. Except as so stated, Bayer denies  
14 the allegations in Paragraph 64 of the Complaint.

15 65. Bayer admits that product labeling for Avelox® was amended on August 15, 2013.  
16 Bayer further states that the content of the product labeling for Avelox® speaks for itself. Bayer  
17 denies that the warnings for Avelox® were inadequate and denies the remaining allegations in  
18 Paragraph 65 of the Complaint.

19 66. Bayer states that the literature referenced in Paragraph 66 of the Complaint speaks for  
20 itself, and denies the allegations in Paragraph 66 to the extent they are inconsistent with the contents  
21 of the literature. Except as so stated, Bayer denies the allegations in Paragraph 66 of the Complaint.

22 **FIRST RESPONSE TO "EQUITABLE TOLLING OF APPLICABLE**

23 **STATUTE OF LIMITATIONS"**

24 67. Bayer incorporates by reference its responses to each and every paragraph in the  
25 Complaint.

26 68. Paragraph 68 of the Complaint states legal conclusions to which no answer is  
27 required. To the extent a response is required, Bayer denies the allegations in Paragraph 68 of the  
28 Complaint.

1           69. Paragraph 69 of the Complaint states legal conclusions to which no answer is  
2 required. To the extent a response is required, Bayer denies the allegations in Paragraph 69 of the  
3 Complaint.

4           70. Paragraph 70 of the Complaint states legal conclusions to which no answer is  
5 required. To the extent a response is required, Bayer denies the allegations in Paragraph 70 of the  
6 Complaint.

7           71. Paragraph 71 of the Complaint states legal conclusions to which no answer is  
8 required. To the extent a response is required, Bayer denies the allegations in Paragraph 71 of the  
9 Complaint.

10          72. Paragraph 72 of the Complaint contains a statement that does not require an  
11 admission or denial, as no allegations are stated.

12                           **FIRST RESPONSE TO “FIRST CAUSE OF ACTION**

13                                   **[Strict Liability]”**

14          73. Bayer denies that Avelox® was defective and denies the remaining allegations in  
15 Paragraph 73 of the Complaint.

16          74. Bayer denies that Avelox® was defective and denies the remaining allegations in  
17 Paragraph 74 of the Complaint.

18          75. Paragraph 75 of the Complaint states legal conclusions to which no answer is  
19 required. Bayer is without knowledge or information sufficient to form a belief as to the truth of the  
20 allegations in Paragraph 75 of the Complaint and therefore denies them. Except as so stated, Bayer  
21 denies the allegations in Paragraph 75 of the Complaint.

22          76. Bayer denies that Avelox® was defective and denies the remaining allegations in  
23 Paragraph 76 of the Complaint.

24          77. Bayer denies that Avelox® was defective and denies the remaining allegations in  
25 Paragraph 77 of the Complaint.

26          78. Bayer denies that Avelox® was defective and denies the remaining allegations in  
27 Paragraph 78 of the Complaint.

28          79. Bayer denies that Avelox® was defective and denies the remaining allegations in

1 Paragraph 79 of the Complaint.

2 WHEREFORE, Bayer demands judgment in their favor and against Plaintiff, dismissing the  
3 Complaint with prejudice, an award of attorneys' fees, interest and costs of suit, and such other and  
4 further relief as the Court deems just and necessary.

5 **FIRST RESPONSE TO "SECOND CAUSE OF ACTION**

6 **[Product Liability – Failure to Warn]**

7 80. Bayer incorporates by reference its responses to each and every paragraph in the  
8 Complaint.

9 81. In response to the allegations in Paragraph 81 of the Complaint, Bayer incorporates  
10 its answer to Paragraph 8 of the Complaint. Except as so stated, Bayer denies the allegations in  
11 Paragraph 81 of the Complaint.

12 82. In response to the allegations in Paragraph 82 of the Complaint, Bayer incorporates  
13 its answer to Paragraph 8 of the Complaint. Except as so stated, Bayer denies the allegations in  
14 Paragraph 82 of the Complaint.

15 83. Bayer denies that Avelox® was defective and that Avelox®'s warnings were  
16 inadequate. Bayer further denies the remaining allegations in Paragraph 83 of the Complaint.

17 84. Bayer denies that Avelox® was defective. Bayer is without knowledge or  
18 information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 84 of  
19 the Complaint and therefore denies them.

20 85. Paragraph 85 of the Complaint states legal conclusions to which no answer is  
21 required. To the extent a response is required, Bayer denies the allegations in Paragraph 85 of the  
22 Complaint.

23 86. Bayer denies that Avelox® was dangerous or unsafe and denies the remaining  
24 allegations in Paragraph 86 of the Complaint.

25 87. Bayer denies that Avelox®'s warnings were inadequate and denies the remaining  
26 allegations in Paragraph 87 of the Complaint.

27 88. Paragraph 88 of the Complaint states legal conclusions to which no answer is  
28 required. To the extent a response may be required, Bayer denies that Avelox®'s warnings were

1 inadequate and denies the remaining allegations in Paragraph 88 of the Complaint.

2 89. Bayer denies that Avelox® was defective. Bayer is without knowledge or  
3 information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 89 of  
4 the Complaint and therefore denies them.

5 90. Paragraph 90 of the Complaint states legal conclusions to which no answer is  
6 required. To the extent a response is required, Bayer denies the allegations in Paragraph 90 of the  
7 Complaint.

8 91. Paragraph 91 of the Complaint states legal conclusions to which no answer is  
9 required. To the extent a response is required, Bayer is without knowledge or information sufficient  
10 to form a belief as to the truth of the allegations in Paragraph 91 of the Complaint and therefore  
11 denies them.

12 92. Bayer denies the allegations in Paragraph 92 of the Complaint.

13 93. Paragraph 93 of the Complaint states legal conclusions to which no answer is  
14 required. To the extent a response may be required, Bayer denies liability for any injury alleged in  
15 the Complaint and denies the remaining allegations in Paragraph 93 of the Complaint. Except as so  
16 stated, Bayer denies the allegations in Paragraph 93 of the Complaint.

17 WHEREFORE, Bayer demands judgment in their favor and against Plaintiff, dismissing the  
18 Complaint with prejudice, an award of attorneys' fees, interest and costs of suit, and such other and  
19 further relief as the Court deems just and necessary.

20 **FIRST RESPONSE TO "THIRD CAUSE OF ACTION**

21 **[Negligence]"**

22 94. Bayer incorporates by reference its responses to each and every paragraph in the  
23 Complaint.

24 95. Paragraph 95 of the Complaint states legal conclusions to which no answer is  
25 required. To the extent a response may be required, Bayer denies that it had any duty to provide  
26 warnings directly to Plaintiff, denies that it breached any applicable duty of care relating to  
27 Plaintiff's claims, denies liability for any injury alleged in the Complaint, and denies the remaining  
28 allegations in Paragraph 95 of the Complaint. Except as so stated, Bayer denies the allegations in

Paragraph 95 of the Complaint.

96. Bayer denies the allegations in Paragraph 96 of the Complaint.

97. Bayer denies the allegations in Paragraph 97 of the Complaint, including all subparts thereof.

98. Bayer denies the allegations in Paragraph 98 of the Complaint.

99. Bayer denies liability for any injury alleged in the Complaint and denies the remaining allegations in Paragraph 99 of the Complaint.

WHEREFORE, Bayer demands judgment in their favor and against Plaintiff, dismissing the Complaint with prejudice, an award of attorneys' fees, interest and costs of suit, and such other and further relief as the Court deems just and necessary.

**FIRST RESPONSE TO "FOURTH CAUSE OF ACTION**

**[Breach of Express Warranty]"**

100. Bayer incorporates by reference its responses to each and every paragraph in the Complaint.

101. Paragraph 101 of the Complaint states legal conclusions to which no answer is required. To the extent a response is required, Bayer admits that Avelox® is indicated to treat certain bacterial infections in adults  $\geq 18$  years of age caused by designated, susceptible bacteria, and is safe and effective when used in accordance with Avelox®'s FDA-approved labeling. Except as so stated, Bayer denies the allegations in Paragraph 101 of the Complaint.

102. Bayer denies the allegations in Paragraph 102 of the Complaint.

103. Bayer denies liability for any injury alleged in the Complaint and denies the remaining allegations in Paragraph 103 of the Complaint.

WHEREFORE, Bayer demands judgment in their favor and against Plaintiff, dismissing the Complaint with prejudice, an award of attorneys' fees, interest and costs of suit, and such other and further relief as the Court deems just and necessary.

**FIRST RESPONSE TO "FIFTH CAUSE OF ACTION**

**[Breach of Implied Warranty]"**

104. Bayer incorporates by reference its responses to each and every paragraph in the

1 Complaint.

2 105. Paragraph 105 of the Complaint states legal conclusions to which no answer is  
3 required. To the extent a response is required, Bayer incorporates its answer to Paragraph 8 of the  
4 Complaint. Bayer further admits that Avelox® is indicated to treat certain bacterial infections in  
5 adults  $\geq 18$  years of age caused by designated, susceptible bacteria, and is safe and effective when  
6 used in accordance with Avelox®'s FDA-approved labeling. Except as so stated, Bayer denies the  
7 allegations in Paragraph 105 of the Complaint.

8 106. Paragraph 106 of the Complaint states legal conclusions to which no answer is  
9 required. To the extent a response is required, Bayer is without knowledge or information sufficient  
10 to form a belief as to the truth of the allegations in Paragraph 106 of the Complaint and therefore  
11 denies them.

12 107. Bayer is without knowledge or information sufficient to form a belief as to the truth  
13 of the allegations in Paragraph 107 of the Complaint and therefore denies them.

14 108. Bayer denies the allegations in Paragraph 108 of the Complaint.

15 109. Bayer denies the allegations in Paragraph 109 of the Complaint.

16 110. Bayer denies liability for any injury alleged in the Complaint and denies the  
17 remaining allegations in Paragraph 110 of the Complaint.

18 WHEREFORE, Bayer demands judgment in their favor and against Plaintiff, dismissing the  
19 Complaint with prejudice, an award of attorneys' fees, interest and costs of suit, and such other and  
20 further relief as the Court deems just and necessary.

21 **FIRST RESPONSE TO "SIXTH CAUSE OF ACTION**

22 **[Fraud]"**

23 111. Bayer incorporates by reference its responses to each and every paragraph in the  
24 Complaint.

25 112. Bayer denies the allegations in Paragraph 112 of the Complaint.

26 113. Bayer denies the allegations in Paragraph 113 of the Complaint, including all subparts  
27 thereof.

28 114. Bayer denies the allegations in Paragraph 114 of the Complaint.

115. Bayer denies the allegations in Paragraph 115 of the Complaint.

116. Bayer denies the allegations in Paragraph 116 of the Complaint.

117. Bayer denies the allegations in Paragraph 114 of the Complaint.

118. Paragraph 118 of the Complaint states legal conclusions to which no answer is required. To the extent a response is required, Bayer denies the allegations in Paragraph 118 of the Complaint.

119. Paragraph 119 of the Complaint states legal conclusions to which no answer is required. To the extent a response may be required, Bayer denies that it had any duty to provide warnings directly to Plaintiff, denies that it breached any applicable duty of care relating to Plaintiff's claims, denies liability for any injury alleged in the Complaint, and denies the remaining allegations in Paragraph 119 of the Complaint. Except as so stated, Bayer denies the allegations in Paragraph 119 of the Complaint.

120. Bayer denies the allegations in Paragraph 120 of the Complaint.

121. Bayer denies liability for any injury alleged in the Complaint and denies the remaining allegations in Paragraph 121 of the Complaint.

WHEREFORE, Bayer demands judgment in their favor and against Plaintiff, dismissing the Complaint with prejudice, an award of attorneys' fees, interest and costs of suit, and such other and further relief as the Court deems just and necessary.

**FIRST RESPONSE TO "SEVENTH CAUSE OF ACTION**

**[Negligent Misrepresentation]"**

122. Bayer incorporates by reference its responses to each and every paragraph in the Complaint.

123. Bayer denies the allegations in Paragraph 123 of the Complaint.

124. Bayer denies the allegations in Paragraph 124 of the Complaint, including all subparts thereof.

125. Bayer denies the allegations in Paragraph 125 of the Complaint.

126. Bayer denies the allegations in Paragraph 126 of the Complaint.

127. Bayer denies the allegations in Paragraph 127 of the Complaint.

1           128.     Bayer denies the allegations in Paragraph 128 of the Complaint.

2           129.     Paragraph 128 of the Complaint states legal conclusions to which no answer is  
3 required. To the extent a response is required, Bayer denies the allegations in Paragraph 128 of the  
4 Complaint.

5           130.     Paragraph 130 of the Complaint states legal conclusions to which no answer is  
6 required. To the extent a response may be required, Bayer denies that it had any duty to provide  
7 warnings directly to Plaintiff, denies that it breached any applicable duty of care relating to  
8 Plaintiff's claims, denies liability for any injury alleged in the Complaint, and denies the remaining  
9 allegations in Paragraph 130 of the Complaint. Except as so stated, Bayer denies the allegations in  
10 Paragraph 130 of the Complaint.

11          131.     Bayer denies the allegations in Paragraph 131 of the Complaint.

12          132.     Bayer denies liability for any injury alleged in the Complaint and denies the  
13 remaining allegations in Paragraph 132 of the Complaint.

14          WHEREFORE, Bayer demands judgment in their favor and against Plaintiff, dismissing the  
15 Complaint with prejudice, an award of attorneys' fees, interest and costs of suit, and such other and  
16 further relief as the Court deems just and necessary.

17                   **FIRST RESPONSE TO "EIGHTH CAUSE OF ACTION**

18                           **[Fraudulent Concealment]**

19          133.     Bayer incorporates by reference its responses to each and every paragraph in the  
20 Complaint.

21          134.     Bayer denies the allegations in Paragraph 134 of the Complaint.

22          135.     Paragraph 135 of the Complaint states legal conclusions to which no answer is  
23 required. To the extent a response is required, Bayer denies the allegations in Paragraph 135 of the  
24 Complaint.

25          136.     Paragraph 136 of the Complaint states legal conclusions to which no answer is  
26 required. To the extent a response may be required, Bayer denies the allegations in Paragraph 135 of  
27 the Complaint.

28          137.     Paragraph 137 of the Complaint states legal conclusions to which no answer is



1 required. To the extent a response may be required, Bayer denies that it had any duty to provide  
2 warnings directly to Plaintiff, denies that it breached any applicable duty of care relating to  
3 Plaintiff's claims, denies liability for any injury alleged in the Complaint, and denies the remaining  
4 allegations in Paragraph 137 of the Complaint. Except as so stated, Bayer denies the allegations in  
5 Paragraph 137 of the Complaint.

6 138. Paragraph 139 of the Complaint states legal conclusions to which no answer is  
7 required. To the extent a response may be required, Bayer denies the allegations in Paragraph 139 of  
8 the Complaint.

9 139. Bayer denies the allegations in Paragraph 139 of the Complaint.

10 WHEREFORE, Bayer demands judgment in their favor and against Plaintiff, dismissing the  
11 Complaint with prejudice, an award of attorneys' fees, interest and costs of suit, and such other and  
12 further relief as the Court deems just and necessary.

13 **FIRST RESPONSE TO "PUNITIVE DAMAGES"**

14 140. Bayer incorporates by reference its responses to each and every paragraph in the  
15 Complaint.

16 141. Bayer denies the allegations in Paragraph 141 of the Complaint.

17 142. Bayer denies the allegations in Paragraph 142 of the Complaint.

18 143. Bayer denies the allegations in Paragraph 143 of the Complaint.

19 144. Bayer denies the allegations in Paragraph 144 of the Complaint.

20 145. Bayer denies the allegations in Paragraph 145 of the Complaint.

21 146. Bayer denies the allegations in Paragraph 146 of the Complaint.

22 147. Bayer denies the allegations in Paragraph 147 of the Complaint.

23 148. Bayer denies liability for any injury alleged in the Complaint and denies the  
24 remaining allegations in Paragraph 148 of the Complaint.

25 149. Bayer denies that Plaintiff is entitled to punitive damages and the denies the  
26 remaining allegations in Paragraph 149 of the Complaint.

27 **FIRST RESPONSE TO "PRAYER FOR RELIEF"**

28 WHEREFORE, Bayer demands judgment in their favor and against Plaintiff, dismissing the

1 Complaint with prejudice, an award of attorneys' fees, interest and costs of suit, and such other and  
2 further relief as the Court deems just and necessary.

3 **SEPARATE DEFENSES**

4 Discovery and investigation may reveal that one or more of the following additional defenses  
5 should be available to Bayer in this matter. Bayer accordingly preserves the right to assert these  
6 separate and additional defenses. Upon completion of discovery, if the facts warrant, Bayer may  
7 withdraw any of these additional defenses as may be appropriate. Bayer further reserves the right to  
8 amend their answer and defenses, and to assert additional defenses and other claims, as discovery  
9 proceeds.

10 Further answering, and by way of additional defense, Bayer states as follows:

11 **FIRST DEFENSE**

12 The Complaint, and each of the alleged causes of action, fails to state a claim against Bayer  
13 upon which relief can be granted.

14 **SECOND DEFENSE**

15 Venue may be improper and/or inconvenient in this Court.

16 **THIRD DEFENSE**

17 Plaintiff may lack capacity or standing to bring this action.

18 **FOURTH DEFENSE**

19 Plaintiff has failed to join necessary or indispensable parties.

20 **FIFTH DEFENSE**

21 Plaintiff's claims may be barred by the doctrine(s) contained in the Restatement (Second) of  
22 Torts § 402A, Comment k, and/or the Restatement (Third) of Torts: Products Liability § 6. The  
23 pharmaceutical product in question is useful and desirable, and any risk claimed by Plaintiff with its  
24 use and the alleged injury, to the extent it exists, is unavoidable.

25 **SIXTH DEFENSE**

26 Plaintiff's claims are governed and barred, in whole or in part, by Sections 2, 4, and 6 of The  
27 Restatement (Third) of Torts (including the comments thereto) because Bayer complied with all  
28 applicable statutes and with the requirements and regulations of the Food and Drug Administration.

1 **SEVENTH DEFENSE**

2 Plaintiff's claims are barred by the applicable Statute of Limitations and Repose, by  
3 operation of law, and because the "discovery rule" does not apply to Plaintiff's allegations or claims.

4 **EIGHTH DEFENSE**

5 All or some of Plaintiff's claims may be barred, in whole or in part, by the doctrines of  
6 waiver, laches, or estoppel.

7 **NINTH DEFENSE**

8 Plaintiff has not suffered any actual injury, loss, or damages because of Plaintiff's alleged use  
9 of Avelox®.

10 **TENTH DEFENSE**

11 Plaintiff's claims may be barred, in whole or in part, because Bayer did not design, promote,  
12 or sell the products which form the basis of Plaintiff's claims.

13 **ELEVENTH DEFENSE**

14 The subject product and/or critical evidence related thereto may have been destroyed, altered,  
15 concealed and/or spoliated by parties other than Bayer.

16 **TWELTH DEFENSE**

17 Bayer specifically denies all allegations of duty, breach, negligence, causation, and all forms  
18 of damages.

19 **THIRTEENTH DEFENSE**

20 Plaintiff's claims may be barred, in whole or in part, by the "learned intermediary" or  
21 "informed intermediary" doctrine.

22 **FOURTEENTH DEFENSE**

23 Plaintiff's claims may be barred, in whole or in part, because Plaintiff's damages or injuries  
24 were caused, in whole or in part, by negligence, fault, or wrongful conduct of Plaintiff or other  
25 parties, and Plaintiff's claims may be barred or limited by the doctrines of comparative fault or  
26 contributory negligence.

27 **FIFTEENTH DEFENSE**

28 The alleged injuries or damages, if any, of the Plaintiff were caused by an intervening or

1 superseding cause and any action on the part of Bayer was not the proximate cause of the alleged  
2 injuries or damages, if any, of the Plaintiff, and the alleged injuries were caused, solely, partially, or  
3 proximately by the intervening actions, omissions, representations, misrepresentations, negligence,  
4 or breach of duty, of other persons, firms, or corporations that Bayer did not control and for whom  
5 Bayer is not legally liable and whose conduct they could not foresee or anticipate.

6 **SIXTEENTH DEFENSE**

7 Plaintiff's alleged damages resulted from new and independent, unforeseeable, superseding  
8 and/or intervening causes unrelated to any conduct of, or any product manufactured or placed in the  
9 stream of commerce by, Bayer.

10 **SEVENTEENTH DEFENSE**

11 Plaintiff's claims are barred in whole or in part because any alleged defect was not known or  
12 not reasonably scientifically knowable at the time the product was manufactured and marketed.

13 **EIGHTEENTH DEFENSE**

14 Plaintiff's alleged damages were not proximately caused by any act or omission of Bayer.

15 **NINETEENTH DEFENSE**

16 All or part of the injuries, damages, and/or losses, if any, sustained by Plaintiff, if proven,  
17 were caused in whole or in part by the acts or omissions of others for whose conduct Bayer is not  
18 responsible and/or resulted from conditions or events unrelated to any conduct by Bayer.

19 **TWENTIETH DEFENSE**

20 Plaintiff's claims may be barred, in whole or in part, by the doctrine of learned consent.

21  
22 **TWENTY-FIRST DEFENSE**

23 Plaintiff was contributorily negligent, and the negligence of Plaintiff was greater than that of  
24 Bayer. Therefore, Plaintiff is barred from recovery.

25 **TWENTY-SECOND DEFENSE**

26 As to the Plaintiff and/or any other entity or person whose conduct or intervening negligence  
27 resulted in the alleged injuries of the Plaintiff, Bayer expressly pleads the doctrine of assumption of  
28 the risk by the Plaintiff and these other persons and/or entities as a bar to the claims of the Plaintiff.

1 **TWENTY-THIRD DEFENSE**

2 Plaintiff's alleged injuries and damages were caused by factors other than, and unrelated to,  
3 Avelox®, including but not limited to pre-existing medical, genetic, and/or environmental  
4 conditions, diseases, or illnesses. Bayer had no control over such factors, nor were such factors due  
5 to or caused by the fault, lack of care, negligence, or breach of any duty by Bayer.

6 **TWENTY-FOURTH DEFENSE**

7 The labeling for the subject product gave full, complete and adequate warnings and  
8 instructions that complied with the applicable federal statutes and regulations. As a matter of law,  
9 where Bayer complied with federal regulations, its conduct cannot give rise to a state law cause of  
10 action for strict liability, negligence, or breach of warranties.

11 **TWENTY-FIFTH DEFENSE**

12 This Court should abstain from adjudicating Plaintiff's claims relating to warnings and  
13 labeling in deference to the interpretation of regulations relating to prescription drug labeling by the  
14 FDA.

15 **TWENTY-SIXTH DEFENSE**

16 To the extent there were any risks associated with the use of the product at issue in this action  
17 that Bayer knew or should have known and that gave rise to a duty to warn, Bayer at all times  
18 discharged such duty through appropriate and adequate warnings in accordance with federal statutes  
19 and regulations and with the existing state of medical and scientific knowledge. In the alternative,  
20 Bayer had no duty to warn persons directly concerning risks, if any, associated with the use of said  
21 medication.

22 **TWENTY-SEVENTH DEFENSE**

23 Plaintiff's claims are barred because Avelox® was neither defective nor unreasonably  
24 dangerous in its design, manufacture, or marketing and was reasonably fit, suitable, and safe for its  
25 intended purpose.

26 **TWENTY-EIGHTH DEFENSE**

27 The benefits of the design and composition of the product outweigh the risks, if any,  
28 associated with it.

1 **TWENTY-NINTH DEFENSE**

2 Plaintiff's claims are barred because Avelox® was designed, manufactured, and marketed in  
3 accordance with the state of the art and when Avelox® left the control of Bayer; no practical and  
4 technically feasible alternative formulation was available that would have prevented the harm for  
5 which Plaintiff seeks to recover without substantially impairing the safety, efficacy, or usefulness of  
6 the product for its intended use.

7 **THIRTIETH DEFENSE**

8 Based on the state of scientific, medical, and technological knowledge existing at the time the  
9 product at issue in this action was allegedly consumed by Plaintiff, it was reasonably safe for its  
10 normal and foreseeable use at all relevant times, or in light of existing reasonably available medical,  
11 scientific, and technological knowledge.

12 **THIRTY-FIRST DEFENSE**

13 Plaintiff's alleged injuries or damages, if any, were the result of misuse or unintended use of  
14 the product or products at issue.

15 **THIRTY-SECOND DEFENSE**

16 If Plaintiff was injured or damaged by a product manufactured or marketed by Bayer, which  
17 Bayer denies, that product was altered, modified, or misused by individuals and/or entities over  
18 whom Bayer had no control or right of control, without Bayer' knowledge, consent, or advice,  
19 following the date of initial manufacture and/or sale of the product, and such alteration,  
20 modification, or misuse caused or contributed to the events alleged in Plaintiff's Complaint.

21 **THIRTY-THIRD DEFENSE**

22 Plaintiff's claims are barred, in whole or in part, because Avelox® is comprehensively  
23 regulated by the United States Food and Drug Administration ("FDA") pursuant to the Federal Food,  
24 Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 et seq., and regulations promulgated thereunder,  
25 and Plaintiffs' claims conflict with the FDCA, with the regulations promulgated by FDA to  
26 implement the FDCA, with the purposes and objectives of the FDCA and the FDA's implementing  
27 regulations, and with the specific determinations by the FDA specifying the language that should be  
28 used in the labeling accompanying Avelox®. Accordingly, Plaintiff's claims are preempted by the

1 Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United  
2 States.

3 **THIRTY-FOURTH DEFENSE**

4 Plaintiff's claims are barred, in whole or in part, by the deference that common law gives to  
5 discretionary actions by the FDA under the FDCA.

6 **THIRTY-FIFTH DEFENSE**

7 Plaintiff's claims purportedly asserted under statutes and regulations relating to prescription  
8 drugs fail, in whole or in part, because those statutes and regulations do not contain or create any  
9 private cause of action.

10 **THIRTY-SIXTH DEFENSE**

11 To the extent Plaintiff's claims are based on alleged misrepresentations or omissions made to  
12 the FDA, such claims are barred by *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341  
13 (2001).

14 **THIRTY-SEVENTH DEFENSE**

15 Plaintiff's warranty-based claims against Bayer are barred in whole or in part on grounds that  
16 Bayer did not make or breach any warranties applicable to Plaintiff.

17 **THIRTY-EIGHTH DEFENSE**

18 Plaintiff's warranty-based claims are barred in whole or in part by Plaintiff's lack of reliance  
19 on such warranties.

20 **THIRTY-NINTH DEFENSE**

21 Plaintiff lacks the requisite privity with Bayer to sustain a claim for breach of express or  
22 implied warranty.

23 **FORTIETH DEFENSE**

24 Plaintiff's warranty-based claims against Bayer are barred in whole or in part to the extent  
25 that Plaintiff failed to give proper or timely notice of any alleged defect or breach of warranty to  
26 Bayer.

27 **FORTY- FIRST DEFENSE**

28 To the extent that Plaintiff relies upon any theory of breach of warranty, such claims are

1 barred for failure of Plaintiff, or Plaintiff's representative, to comply with all applicable  
2 requirements for a breach of warranty claim. Bayer specifically pleads as to any breach of warranty  
3 claim all affirmative defenses under the Uniform Commercial Code, as enacted in the State of  
4 California, existing and which may arise in the future.

5 **FORTY-SECOND DEFENSE**

6 Plaintiff's Complaint fails to state a claim for fraud, misrepresentation, deceit, concealment,  
7 suppression and/or omission, and fails to allege the circumstances constituting fraud with the  
8 required particularity.

9 **FORTY-THIRD DEFENSE**

10 Bayer specifically pleads as to Plaintiff's allegations of fraud, misrepresentation, deceit,  
11 concealment, suppression and/or omission, all affirmative defenses available to Bayer under the  
12 rules and statutes of California and any state whose law is deemed to apply in this case, and under  
13 any common law principles of California and any state whose law is deemed to apply in this case.

14 **FORTY-FOURTH DEFENSE**

15 Bayer neither owed nor breached any duty to Plaintiff and did not mislead Plaintiff or anyone  
16 claiming under them to their prejudice. Further, Bayer committed no act or omission that California  
17 law specifically declares to be fraudulent.

18 **FORTY-FIFTH DEFENSE**

19 To the extent that any of Plaintiff's claims can be, or are construed as, alleging a violation of  
20 consumer protection laws, Bayer specifically pleads all affirmative defenses available to Bayer  
21 under the rules and statutes of any state whose law is deemed to apply in this case, and under the  
22 common law principles of any state whose law is deemed to apply in this case.

23 **FOURTY-SIXTH DEFENSE**

24 Plaintiffs' damages, if any, may be limited, in whole or in part, by Plaintiffs' failure to  
25 mitigate.

26 **FOURTY-SEVENTH DEFENSE**

27 Upon information and belief, each item of economic loss alleged in the Complaint was, or  
28 with reasonable certainty will be, replaced or indemnified in whole or in part from collateral sources.



1 To the extent Plaintiff is seeking recovery for benefits entitled to be received or actually received  
2 from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this  
3 action under applicable law.

4 **FOURTY-EIGHTH DEFENSE**

5 Bayer is entitled to any set-offs or deductions from any damages awarded under the doctrine  
6 of Collateral Source, both under common law and by statute.

7 **FOURTY-NINTH DEFENSE**

8 If Plaintiff recovers damages, Bayer will be entitled to contribution, apportionment and/or  
9 indemnification to the extent such damages were sustained, in whole or in part, by reason of any  
10 wrongful conduct attributed to defendants other than Bayer.

11 **FIFTIETH DEFENSE**

12 Plaintiff's damages, if any, may be barred, limited, or offset in the amount of any  
13 reimbursement received by Plaintiff as a result of any insurance or other health benefits plan, or any  
14 amounts paid by any insurance or other health benefits plan.

15 **FIFTY-FIRST DEFENSE**

16 To the extent Plaintiff has settled or will in the future settle with any person or entity with  
17 respect to the injuries asserted in the Complaint, the liability of Bayer, if any, should be reduced  
18 accordingly. Pursuant to the common law right to credits, reductions and setoffs, and other  
19 applicable law, any settlement reached between Plaintiff and a named defendant in this action shall  
20 reduce the amount of Plaintiff's recovery by the stipulated amount of the agreement, or in the  
21 amount of consideration paid, whichever is greater.

22 **FIFTY-SECOND DEFENSE**

23 Plaintiff's Complaint fails to state a claim on which relief can be granted for joint and several  
24 liability.

25 **FIFTY-THIRD DEFENSE**

26 Plaintiff's claims may be barred, in whole or in part, under the doctrine of primary  
27 jurisdiction, in that the pertinent conduct of Bayer and all its activities with respect to the subject  
28 product Avelox® have been and are conducted under the supervision of FDA.

1 **FIFTY-FOURTH DEFENSE**

2 Any claims by Plaintiff relating to alleged communications with regulatory agencies of the  
3 United States government are barred in whole or in part by operation of applicable law, including  
4 First and Fourteenth Amendment rights to petition the government.

5 **FIFTY-FIFTH DEFENSE**

6 Plaintiff's claims are barred in whole or in part because the commercial speech relating to  
7 Avelox® was not false or misleading and is protected under the First Amendment to the United  
8 States Constitution and by applicable state constitutional provisions.

9 **FIFTY-SIXTH DEFENSE**

10 To the extent Plaintiff's claims relate to Bayer's advertising, public statements, lobbying, or  
11 other activities protected by the First Amendment to the Constitution of the United States or by the  
12 California Constitution, or other applicable state constitution, such claims are barred.

13 **FIFTY-SEVENTH DEFENSE**

14 Any claims against Bayer are barred by reason of prescription and/or any preemption  
15 periods.

16 **FIFTY-EIGHTH DEFENSE**

17 The claims made by Plaintiff are precluded by res judicata and/or collateral estoppel  
18 principles, to the extent that there are prior actions raising the same claims and issues as are raised in  
19 this action, which prior actions were resolved after full and fair litigation.

20 **FIFTY-NINTH DEFENSE**

21 Plaintiff's Complaint fails to state a claim on which relief can be granted as to costs and  
22 disbursements, attorney fees, expert fees, expenses, pre-judgment interest, post-judgment interest,  
23 refund, unjust enrichment, disgorgement, restitution, or treble damages.

24 **SIXTIETH DEFENSE**

25 Plaintiff's Complaint fails to state a claim against Bayer upon which relief can be granted for  
26 punitive or exemplary damages.

27 **SIXTY-FIRST DEFENSE**

28 Bayer denies any conduct for which punitive or exemplary damages could or should be

1 awarded and denies that Plaintiff has produced evidence sufficient to support or sustain the  
2 imposition of punitive damages against Bayer pursuant to the applicable standards of proof.

3 **SIXTY-SECOND DEFENSE**

4 To the extent Plaintiff seeks recovery of punitive or exemplary damages against Bayer,  
5 unless Bayer's liability for punitive damages and the appropriate amount of punitive damages are  
6 required to be established by clear and convincing evidence, any award of punitive damages would  
7 violate Bayer's due process rights guaranteed by the Fourteenth Amendment to the United States  
8 Constitution and by the applicable state constitution, and would be improper under the common law  
9 and public policies of that state.

10 **SIXTY-THIRD DEFENSE**

11 To the extent Plaintiff seeks recovery of punitive or exemplary damages against Bayer, any  
12 such claim of Plaintiff for punitive damages against Bayer cannot be maintained, because an award  
13 of punitive damages under applicable law would be unlawful and unauthorized, and would be void  
14 for vagueness, both facially and as applied, as a result of, among other deficiencies, the absence of  
15 adequate notice of what conduct is subject to punishment; the absence of adequate notice of what  
16 punishment may be imposed; and the absence of a predetermined limit, such as a maximum multiple  
17 of compensatory damages or a maximum amount, on the amount of punitive damages that a jury  
18 may impose, all in violation of the due process clause of the Fourteenth Amendment to the United  
19 States Constitution, and by that applicable state constitution, and the common law and public  
20 policies of that state.

21 **SIXTY-FOURTH DEFENSE**

22 To the extent Plaintiff seeks recovery of punitive or exemplary damages against Bayer, any  
23 such claim of Plaintiff for punitive damages against Bayer cannot be maintained, because any award  
24 of punitive damages under applicable law would be by a jury that (1) is not provided standards of  
25 sufficient clarity for determining the appropriateness, and the appropriate size, of a punitive damages  
26 award, (2) is not adequately instructed on the limits on punitive damages imposed by the applicable  
27 principles of deterrence and punishment, (3) is not expressly prohibited from awarding punitive  
28 damages, or determining the amount of an award of punitive damages, in whole or in part, on the

1 basis of invidiously discriminatory characteristics, including the residence, wealth, and corporate  
2 status of Bayer, (4) is permitted to award punitive damages under a standard for determining liability  
3 for punitive damages that is vague and arbitrary and does not define with sufficient clarity the  
4 conduct or mental state that makes punitive damages permissible, (5) is permitted to award punitive  
5 damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that  
6 was not directed, or did not proximately cause harm, if any, to Plaintiff, (6) is permitted to award  
7 punitive damages in an amount that is not both reasonable and proportionate to the amount of harm,  
8 if any, to Plaintiff and to the amount of compensatory damages, if any and (7) is not subject to  
9 adequate trial court and appellate judicial review for reasonableness and furtherance of legitimate  
10 purposes on the basis of objective standards. Any such verdict would violate Bayer's due process  
11 rights guaranteed by the Fourteenth Amendment to the United States Constitution and by the due  
12 process and equal protection provisions of the applicable state constitution, and would be improper  
13 under the common law and public policies of that state.

#### 14 **SIXTY-FIFTH DEFENSE**

15 To the extent Plaintiff seeks recovery of punitive or exemplary damages against Bayer, any  
16 award of punitive damages based on anything other than Bayer's conduct in connection with the  
17 design, manufacture, and sale of the specific Avelox® product that is the subject of this lawsuit  
18 would violate the due process clause of the Fourteenth Amendment to the United States Constitution  
19 and the due process provisions of the applicable state constitution, and would be improper under the  
20 common law and public policies of that state, because any other judgment for punitive damages in  
21 this case cannot protect Bayer against impermissible multiple punishment for the same wrong and  
22 against punishment for extra territorial conduct, including especially conduct that is lawful in states  
23 other than the applicable state. In addition, any such award would violate principles of comity under  
24 the laws of that state.

#### 25 **SIXTY- SIXTH DEFENSE**

26 Plaintiff cannot recover punitive or exemplary damages against Bayer because such an  
27 award, which is penal in nature, would violate Bayer's rights under the United States Constitution  
28 and any applicable state constitution, unless Bayer is afforded the same procedural safeguards as are

1 criminal defendants.

2 **SIXTY-SEVENTH DEFENSE**

3 Any imposition of punitive or exemplary damages in this case against Bayer would  
4 contravene the Commerce Clause of the United States Constitution, in that such an award would  
5 constitute an undue and unreasonable burden on interstate commerce.

6 **SIXTY-EIGHTH DEFENSE**

7 With respect to Plaintiff's demand for punitive or exemplary damages, Bayer incorporates by  
8 reference any and all standards or limitations regarding the determination and enforceability of  
9 punitive or exemplary damages awards under applicable state law.

10 **SIXTY-NINTH DEFENSE**

11 No act or omission of Bayer was intentional, fraudulent, malicious, reckless, in any way  
12 morally culpable, or made with conscious, malicious, or intentional disregard for the health and  
13 well-being of Plaintiff or others. Bayer asserts all statutory or judicial protections from punitive or  
14 exemplary damages that are available under applicable law, and any award of punitive or exemplary  
15 damages is barred.

16 **SEVENTIETH DEFENSE**

17 Plaintiff's claim for punitive damages against Bayer cannot be sustained because, in all  
18 respects pertinent to this action, Bayer complied with applicable industry standards and did not  
19 engage in a deliberate course of conduct which knowingly endangered those using Avelox®.

20 **SEVENTY-FIRST DEFENSE**

21 Plaintiff's Complaint seeks damages in excess of those permitted by law. Bayer asserts any  
22 statutory or judicial protection from punitive or exemplary damages that is available under the  
23 applicable law, and any award of punitive or exemplary damages is barred.

24 **SEVENTY-SECOND DEFENSE**

25 The imposition of punitive or exemplary damages would violate the open court provision(s)  
26 of applicable state constitution(s) and other applicable law.

27 **SEVENTY-THIRD DEFENSE**

28 Bayer gives notice that they intend to rely upon other defenses that may become apparent

1 during the course of the litigation, and reserve the right to amend this Answer to assert any such  
2 defenses. Bayer is entitled to, and claims the benefit of, all defenses and presumptions set forth in or  
3 arising from any rule of law or statute, or any other applicable federal or state law.

4 **SEVENTY-FOURTH DEFENSE**

5 Some or all of Plaintiff's claims and/or damages, if any, may be barred, limited, or offset by  
6 the law of other states that may govern under California's choice of law provisions and resulting  
7 application of law from other jurisdictions such as Tennessee. These may include, without  
8 limitation, Tennessee's applicable statute of limitations, its modified comparative fault doctrine, and  
9 limitations on the award of non-economic and punitive damages.

10 **SEVENTY-FIFTH DEFENSE**

11 Bayer adopts and incorporates by reference any and all affirmative defenses asserted by other  
12 defendants in this lawsuit to the extent such affirmative defenses are not raised herein and are  
13 consistent with the defenses raised by Bayer.

14 **SEVENTY-SIXTH DEFENSE**

15 Bayer reserves the right to amend their Answer to assert additional defenses upon completion  
16 of further investigation and discovery.

17 **DEMAND FOR JURY TRIAL**

18 Bayer specifically requests and demands a trial by jury as to all issues so triable.

19 WHEREFORE, Defendant Bayer HealthCare Pharmaceuticals, Inc. prays that:

20 (1) Plaintiff takes nothing by reason of the Complaint;

21 (2) the Complaint be dismissed in its entirety and that a Judgment against Plaintiff  
22 and in favor of Bayer be entered;

23 (3) Bayer be awarded their costs and expenses; and

24 //

25 //

26 //

1                   (4)     this Court award Bayer any other and general or specific relief as this Court  
2 may deem just and proper.

3 Date: October 3, 2014

SHOOK, HARDY & BACON L.L.P.

4  
5 By:   /s/ Alicia J. Donahue  
          Alicia J. Donahue

6 Attorneys for Defendants  
7 BAYER HEALTHCARE PHARMACEUTICALS,  
8 INC. and MERCK & CO., INC.  
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